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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,665	03/16/2004	Kinneret Savitzky	08909.0004-01	4726

7590

10/31/2006

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EXAMINER

DAVIS, MINH TAM B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/800,665

Applicant(s)

SAVITZKY ET AL.

Examiner

MINH-TAM DAVIS

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 36-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 36, drawn to SEQ ID NO:12, fragments, analogues thereof, classified in class 530, subclass 350.
- II. Claims 37-39, drawn to a method for identifying compounds which is an activator or deactivator of KLk-2 variant product, classified in class 435, subclass 7.1.

Claim 43 is a linking claim, linking groups III-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 43. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP, 804.01.

- III. Claims 40-43, drawn to a method for detecting the presence of prostate cancer, classified in class 435, subclass 7.1.

IV. Claims 40-43, drawn to a method for detecting the predisposition to prostate cancer, classified in class 435, subclass 7.1.

Further, this application contains claims 40-43 directed to the following patentably distinct species:

Detect the level of the amino acid sequences of KLK2 variants.

Detect the ratio of the level of the amino acid sequences of KLK2 variants in different samples.

The inventions are distinct, each from each other because of the following reasons:

A. The inventions of Groups II-IV are materially distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The inventions of Groups II-IV are materially distinct methods, which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Further, the method of detecting prostate cancer or detecting predisposition to prostate cancer, a method of identifying an activator or deactivator of a polypeptide are all unrelated as they have different objectives and modes of operation, and differ in method steps, and reagents. For diagnosis of prostate cancer or susceptibility to prostate cancer, using a polypeptide, quantitation of a labeled antibody that binds specifically to said polypeptide may be used. For identifying an activator or deactivator of a polypeptide, an assay for the activity of polypeptide may be used. Thus, each group is unrelated as they comprise distinct steps, which

demonstrates that each method has different mode of operation. For these reasons the Inventions II-IV are patentably distinct.

Furthermore, the examination of all groups would require different searches in the U.S. patent shoes and the scientific literature and would require the consideration of different patentability issues. There may be journal articles devoted solely to detecting the presence of prostate cancer, which would not have described methods of detecting the susceptibility to prostate cancer, or a method for identifying an activator or deactivator of a polypeptide, or vice versa .

As such, it would be burdensome to search the inventions of Groups 19-36, 49-60 together.

B. The invention of Group I and the methods of Groups (II-IV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product (see MPEP 806.05(h)). In the instant case the polypeptides product as claimed can be used in a materially different process such as in making an antibody, in addition to treating a disorder.

Searching the inventions of Group I and Groups (II-IV) together would impose serious search burden. The inventions of Group I and Groups (II-IV) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the searches for the polypeptide and the method for identifying an activator or deactivator or the method of detecting the presence of or the susceptibility to prostate cancer, using the polypeptide are not coextensive.

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The search for Groups (II-IV) would require a text search for the method for identifying an activator or deactivator or the method of detecting the presence of or the susceptibility to prostate cancer, in addition to a search for the polypeptide. Moreover, even if the polypeptide product were known, the method for identifying an activator or deactivator or the method of detecting the presence of or the susceptibility of prostate cancer, which uses the product may be novel and unobvious, in view of the preamble or active steps.

Further, the species are independent or distinct because detecting the level of a polypeptide or the ratio of the levels of a polypeptide in different samples require different mode of operations, different objectives, method steps, and criteria for success.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted, even though the requirement be traversed (37 CFR 1.143).

If any one of groups III-IV is elected, Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits, and a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

MINH TAM DAVIS
October 12, 2006